

Immunoassay Market - North America and Country Analysis: Focus on Product, Specimen, Application, End User, and Country Analysis - Analysis and Forecast, 2025-2035

<https://marketpublishers.com/r/IB8AFB92035BEN.html>

Date: June 2025

Pages: 0

Price: US\$ 4,900.00 (Single User License)

ID: IB8AFB92035BEN

Abstracts

Hard copy option is available on any of the options above at an additional charge of \$500. Please email us at order@marketpublishers.com with your request.

This report will be delivered in 7-10 working days. Introduction to North America Immunoassay Market

An immunoassay is a laboratory technique used to detect and quantify specific substances, such as proteins, hormones, or drugs, in a sample by using antibodies or antigens. It works on the principle of antigen-antibody binding, where the presence of the target substance is measured through a color change or fluorescence. Immunoassays are commonly used in diagnostics, research, and drug testing.

The market is driven by advancements in healthcare, increasing disease prevalence, and a shift toward precision diagnostics. The escalating incidence of chronic conditions such as diabetes, cardiovascular diseases, and cancer in North America significantly propels the demand for diagnostic tools like immunoassays. For instance, according to a 2022 study published in the Journal of the American Medical Association (JAMA), nearly 50% of adults in the U.S. suffer from one or more chronic conditions, driving the need for diagnostic solutions. Immunoassays play a pivotal role in the early detection of such diseases, improving patient outcomes by enabling timely treatment interventions.

Moreover, recent innovations in immunoassay technology, including multiplex assays and microfluidic devices, have significantly improved diagnostic efficiency. The Clinical Chemistry and Laboratory Medicine (CCLM) journal published a study in 2021

highlighting the impact of automated immunoassay systems, which have drastically increased throughput and reduced human error in diagnostic labs. These advancements are expected to continue driving the adoption of immunoassays in both clinical and research settings. Also, the approval of high-throughput immunoassay systems, such as Abbott's ARCHITECT i1000SR (FDA-approved in 2020), highlights how technological advancements are meeting the growing demand for rapid and precise diagnostic solutions. These systems are extensively used in hospitals and reference laboratories throughout North America for their speed and efficiency in detecting infectious diseases and chronic conditions.

Furthermore, the growing focus on personalized or precision medicine has fueled the demand for more specific and accurate diagnostic tools. Immunoassays, by offering precise detection of biomarkers, are increasingly used to tailor treatments to individual patients. As noted in *The Lancet Oncology* (2020), immunoassays have become essential in monitoring treatment responses in oncology, further expanding their role in disease management.

Despite their clinical importance, immunoassay systems are often expensive due to the cost of reagents, complex machinery, and the requirement for specialized infrastructure. The American Journal of Clinical Pathology published a study in 2020 discussing the financial barriers that limit smaller healthcare facilities from adopting high-end diagnostic technologies, which may reduce market accessibility in low-resource settings.

In addition, immunoassay technologies are subject to stringent regulatory oversight, particularly in North America where the U.S. Food and Drug Administration (FDA) regulates diagnostic tools. A 2021 article in *Regulatory Toxicology and Pharmacology* described the challenges faced by manufacturers in obtaining FDA approval for new immunoassay systems, citing lengthy approval times and complex clinical validation requirements as significant hurdles. Delays in the regulatory process can hinder the introduction of innovative diagnostic tools. Also, the operation of immunoassay systems requires strict adherence to protocols for sample collection, storage, and handling. A 2022 study published in *Laboratory Medicine* highlighted the significant impact of pre-analytical variables (such as improper sample handling) on the accuracy of immunoassay results. These operational issues can undermine the effectiveness of immunoassays, especially in settings with less control over sample integrity.

Key players in the market are Danaher Corporation, Siemens Healthineers, F. Hoffmann-La Roche Ltd., Thermo Fisher Scientific, Inc., Merck KGaA, DiaSorin S.p.A., QuidelOrtho Corporation, Bio-Rad Laboratories, bioMérieux, Inc., and Meridian Bioscience.

Market Segmentation:

Segmentation 1: by Product

Reagents and Kits

Analyzers

Reagents and Kits to Lead the North America Immunoassay Market (by Product Type)

Reagents and kits are essential for performing immunoassay tests, which are widely used for detecting diseases such as cancer, cardiovascular diseases, diabetes, and infections. A 2021 article published in the Journal of Clinical Microbiology noted that the demand for diagnostic kits, including immunoassay-based kits, has surged due to the increasing prevalence of chronic and infectious diseases. Moreover, reagents and kits offer a cost-effective solution for diagnostic testing compared to the high initial investment in immunoassay instruments and equipment. A 2020 review published in Laboratory Medicine highlighted that while instruments like analyzers require substantial upfront costs, reagents, and kits are relatively low-cost consumables that significantly reduce the operational costs for healthcare providers. This affordability is particularly important for smaller labs or those with high patient throughput, which need to manage both cost and quality of care.

Segmentation 2: by Specimen

Blood

Saliva

Urine

Others

Segmentation 3: by Application

Infectious Diseases

Cardiology

Autoimmune Disorders

Oncology

Drug Monitoring and Testing

Others

Segmentation 4: by End User

Hospitals and Clinics

Clinical Laboratories

Pharmaceutical and Biotechnology Companies

Others

Segmentation 5: by Country

U.S.

Canada

U.S. Region to Lead the North America Immunoassay Market (by Country)

The U.S. dominates the North American immunoassay market due to a combination of factors, including advanced healthcare infrastructure, a robust regulatory framework, substantial investments in medical research, and a high prevalence of chronic diseases. The U.S. healthcare system is highly developed, with cutting-edge technologies and a broad network of healthcare providers. According to a study published in Health Affairs (2021), the U.S. spends a significant portion of its GDP on healthcare (around 18% in 2020), which facilitates the rapid adoption of advanced diagnostic technologies,

including immunoassays. This infrastructure supports the integration of immunoassay systems into hospitals, clinical laboratories, and research settings, contributing to the country's market leadership. Moreover, the U.S. is home to several leading companies in the immunoassay market, including Abbott Laboratories, Thermo Fisher Scientific, and Roche Diagnostics. According to a 2021 study in Clinical Chemistry, these companies contribute to the innovation and commercialization of new immunoassay platforms that drive market growth. The dominance of these companies in the U.S. contributes to the country's leadership in the North American market by driving technological advancements and expanding access to immunoassay-based diagnostics. Furthermore, the presence of these major manufacturers has created a competitive environment that fosters continuous improvements in product offerings.

Contents

Executive Summary
Scope and Definition
Market/Product Definition
Key Questions Answered
Analysis and Forecast Note

1. MARKETS: INDUSTRY OUTLOOK

1.1 Trends: Current and Future Impact Assessment
1.2 R&D Review
 1.2.1 Patent Filing Trend by Year
1.3 Regulatory Landscape
1.4 Market Dynamics
 1.4.1 Market Drivers
 1.4.2 Market Restraints
 1.4.3 Market Opportunities

2. NORTH AMERICA IMMUNOASSAY MARKET, BY PRODUCT

2.1 Reagents and Kits
2.2 Analyzers

3. NORTH AMERICA IMMUNOASSAY MARKET, BY SPECIMEN

3.1 Blood
3.2 Saliva
3.3 Urine
3.4 Others

4. NORTH AMERICA IMMUNOASSAY MARKET, BY APPLICATION

4.1 Infectious Diseases
4.2 Cardiology
4.3 Autoimmune Disorders
4.4 Oncology
4.5 Drug Monitoring and Testing
4.6 Others

5. NORTH AMERICA IMMUNOASSAY MARKET, BY END USER

- 5.1 Hospitals and Clinics
- 5.2 Clinical Laboratories
- 5.3 Pharmaceutical and Biotechnology Companies
- 5.4 Others

6. NORTH AMERICA IMMUNOASSAY MARKET, BY REGION

- 6.1 U.S.
- 6.2 Canada

7. COMPETITIVE LANDSCAPE AND COMPANY PROFILING

- 7.1 Competitive Landscape
 - 7.1.1 Mergers and Acquisitions
 - 7.1.2 Synergistic Activities
 - 7.1.3 Product Launch and Approval Activities
 - 7.1.4 Expansion, Funding, and Other Activities
- 7.2 Company Profiles
 - 7.2.1 Abbott Laboratories
 - 7.2.1.1 Company Overview
 - 7.2.1.2 Product Offering
 - 7.2.1.3 Key Competitors of the Company
 - 7.2.1.4 Analyst Perspective
 - 7.2.2 Danaher Corporation
 - 7.2.2.1 Company Overview
 - 7.2.2.2 Product Offering
 - 7.2.2.3 Key Competitors of the Company
 - 7.2.2.4 Analyst Perspective
 - 7.2.3 Siemens Healthineers
 - 7.2.3.1 Company Overview
 - 7.2.3.2 Product Offering
 - 7.2.3.3 Key Competitors of the Company
 - 7.2.3.4 Analyst Perspective
 - 7.2.4 F. Hoffmann-La Roche Ltd.
 - 7.2.4.1 Company Overview
 - 7.2.4.2 Product Offering

- 7.2.4.3 Key Competitors of the Company
- 7.2.4.4 Analyst Perspective
- 7.2.5 Thermo Fisher Scientific, Inc.
 - 7.2.5.1 Company Overview
 - 7.2.5.2 Product Offering
 - 7.2.5.3 Key Competitors of the Company
 - 7.2.5.4 Analyst Perspective
- 7.2.6 Merck KGaA
 - 7.2.6.1 Company Overview
 - 7.2.6.2 Product Offering
 - 7.2.6.3 Key Competitors of the Company
 - 7.2.6.4 Analyst Perspective
- 7.2.7 DiaSorin S.p.A.
 - 7.2.7.1 Company Overview
 - 7.2.7.2 Product Offering
 - 7.2.7.3 Key Competitors of the Company
 - 7.2.7.4 Analyst Perspective
- 7.2.8 QuidelOrtho Corporation
 - 7.2.8.1 Company Overview
 - 7.2.8.2 Product Offering
 - 7.2.8.3 Key Competitors of the Company
 - 7.2.8.4 Analyst Perspective
- 7.2.9 Bio-Rad Laboratories
 - 7.2.9.1 Company Overview
 - 7.2.9.2 Product Offering
 - 7.2.9.3 Key Competitors of the Company
 - 7.2.9.4 Analyst Perspective
- 7.2.10 bioMérieux, Inc.
 - 7.2.10.1 Company Overview
 - 7.2.10.2 Product Offering
 - 7.2.10.3 Key Competitors of the Company
 - 7.2.10.4 Analyst Perspective
- 7.2.11 Meridian Bioscience
 - 7.2.11.1 Company Overview
 - 7.2.11.2 Product Offering
 - 7.2.11.3 Key Competitors of the Company
 - 7.2.11.4 Analyst Perspective
- 7.2.12 Other Companies

8. RESEARCH METHODOLOGY

I would like to order

Product name: Immunoassay Market - North America and Country Analysis: Focus on Product, Specimen, Application, End User, and Country Analysis - Analysis and Forecast, 2025-2035

Product link: <https://marketpublishers.com/r/IB8AFB92035BEN.html>

Price: US\$ 4,900.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/IB8AFB92035BEN.html>